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10/009,083

03/20/2002

George Endel Deckner

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02/23/2005

THE PROCTER & GAMBLE COMPANY
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EXAMINER

QAZI, SABIHA NAIM

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,083

Applicant(s)

DECKNER ET AL.

Examiner

Sabiha Qazi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Final Office Action on Merits

Acknowledgement is made of the response filed on October 21, 2004. Claims 1-36 are pending. No claim is allowed. This application is a 371 national stage entry of PCT/US00/13842, filed on May 19, 2000. This application claims priority from PCT/US00/13842.

Applicants' arguments were fully considered but are not found persuasive.

Response to Arguments

Election with Traverse

The Election/Restriction Requirement is withdrawn.

Rejection Under 35 USC § 102(e)

Applicants argue that GATTO et al (US Patent No. 6570054) does not teach each and every element in claims 1 and 30. "For, [*sic*] example, Gatto discloses an article having a skin care composition that is solid or semisolid at 40°C because its' melt temperature is 35°C. Therefore, Gatto cannot anticipate the Applicants' claims 1 and 30."¹

The Examiner respectfully disagrees.

GATTO et al discloses, "The composition can also be applied to a given component (e.g., topsheet, cuffs, sides, waist, etc.), at the converting site or by the material supplier, before it is combined with the other raw materials to form a finished disposable absorbent product. **Again, the composition can be applied to other zones of the article such that the composition will**

¹ Response to Arguments; Filed October 21, 2004; Page 8 of 11

Art Unit: 1616

migrate to one or more wearer contacting surfaces during use. The composition is typically applied from a melt thereof to the article. In a preferred embodiment, the composition fully melts at a temperature significantly above room temperature, it is usually applied as a heated composition to the article. **Typically, the composition is heated to a temperature in the range from about 35°C to about 150°C, preferably from 40°C to about 100°C, prior to being applied to the article.** The skin care ingredient may be added to the composition prior to or after heating. Special care should be taken when heat-sensitive ingredients are used, for example, protease inhibitors or enzyme inhibitors.”²

As is clear from the cited text above, the reference directly discloses the instant invention. The immobilizing agent used in the instant invention, behenyl alcohol in the examples of the Specification, is disclosed in the examples of the reference.³ **Of further note, the instant invention's range is within the range of the reference.**

Even if the reference does not teach the range, it has been established that normally, change in temperature, concentration, range, etc. is not a patentable modification; however, such changes may impart patentability to a process if the ranges claimed produce a new and unexpected result which is different in kind and not merely in degree from results of prior art; such ranges are termed "critical" ranges, and applicant has burden of proving such criticality; even though applicant's modification results in great improvement and utility over prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art; more particularly, where the general conditions of the claim are disclosed in the prior art, it is not

² See line 35 to line 55 in column 35.

³ See Table 3 to Table 5.

Art Unit: 1616

inventive to discover optimum or workable ranges by routine experimentation. In re Aller et al. 105 USPQ 233.

The Examiner does not find any criticality.

Rejection Under 35 USC § 103(a)

The Applicants claim that the Specification discusses criticality of the temperature at which the skin care composition is semisolid and solid on page 22, lines 27-34 to page 23, “lines” 23 and the criticality of the viscosity ranges on page 23, lines 25-35 to page 24, lines 1-2.⁴

None of the referred citations of the Specification discuss the criticality of the temperature at which the skin care composition is semisolid and solid or the criticality of the viscosity ranges.

As a matter of fact, the prior art teaches the range of the temperature, the specific immobilizing agents (Specifically behenyl alcohol) and all the components as presently claimed.

The Applicants argue, “...the specification makes it clear that the Applicants chose different parameters for the skin care composition to get results that meet needs previously unsatisfied by the prior art.”⁵ What are those parameters? Where is the criticality? What are the results that meet needs previously unsatisfied by the prior art?

One skilled in the art would have been motivated to prepare the presently claimed invention because of the combination of OSBORN et al (WO 98/55158), VAN RIJSWIJCK et al (WO 99/12530), and ROE et al (WO 99/22684).

⁴ Response to Arguments; Filed October 21, 2004; Page 10 of 11

Art Unit: 1616

In absence of any criticality, the instant invention is considered *prima facie* obvious.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-36 are rejected under 35 U.S.C. 102(e) as being anticipated by GATTO et al (US 6570054 B1). GATTO et al discloses an absorbent article having a stable skin care composition disposed on its skin-contacting surface. See the entire document, especially the abstract, Tables 1-5, claims, lines 5-43 in col. 9, as well as the specific citations cited below.

⁵ Response to Arguments; Filed October 21, 2004; Page 11 of 11

Art Unit: 1616

GATTO et al discloses, "The composition can also be applied to a given component (e.g., topsheet, cuffs, sides, waist, etc.), at the converting site or by the material supplier, before it is combined with the other raw materials to form a finished disposable absorbent product. **Again, the composition can be applied to other zones of the article such that the composition will migrate to one or more wearer contacting surfaces during use.** The composition is typically applied from a melt thereof to the article. In a preferred embodiment, the composition fully melts at a temperature significantly above room temperature, it is usually applied as a heated composition to the article. **Typically, the composition is heated to a temperature in the range from about 35°C to about 150°C, preferably from 40°C to about 100°C, prior to being applied to the article.** The skin care ingredient may be added to the composition prior to or after heating. Special care should be taken when heat-sensitive ingredients are used, for example, protease inhibitors or enzyme inhibitors."⁶

The immobilizing agent used in the instant invention, behenyl alcohol in the examples of the Specification, is disclosed in the examples of the reference.⁷

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

⁶ See line 35 to line 55 in column 35.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

⁷ See Table 3 to Table 5.

Art Unit: 1616

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of OSBORN et al (WO 98/55158), VAN RIJSWIJCK et al (WO 99/12530), and ROE et al (WO 99/22684). The presently claimed invention is generically taught by the prior art.

OSBORN et al teaches an absorbent device that is pretreated with an emollient composition. The preferred melting points of the immobilizing agents are “of at least about 40 degrees Celsius”.⁸ See the entire document, especially the abstract, examples, claims, the third paragraph on page 21, the last paragraph on page 22, and all of page 23.

VAN RIJSWIJCK et al teaches a skin care composition that provides a therapeutic and/or protective skin benefit upon transfer to the skin by a device. The preferred melting points of the immobilizing agents are “of at least about 40 degrees Celsius.”⁹ See the entire document, especially the abstract, claims, examples, the first paragraph on page 13, all of page 14, and the first & second paragraphs on page 19, and claim 10.

ROE et al teaches a skin care composition to maintain and/or improve skin health of the wearer upon transfer during use. It also teaches semisolid compositions. See the entire document, especially the abstract, examples, claims, and the first paragraph of page 41.

Instant claims differ from the prior art in claiming a broader scope.

It would have been obvious to one skilled in the art at the time of invention to prepare an absorbent article comprising a body contacting surface and an absorbent core by containing a skin care composition because the prior art teaches it. There is motivation to prepare the

⁸ See second to last paragraph on page 28.

Art Unit: 1616

presently claimed invention by selecting the ingredients taught by the prior art *supra* for the same use. The prior art teaches absorbent article, the composition, the immobilizing agent, the melting point of the temperature (solid or semisolid at 40 degrees Celsius), and all other ingredients.

The Examiner notes the proportions, ranges, ratios, concentrations, and temperatures are claimed in various independent claims. It has been established that normally, change in temperature, concentration, or both, is not a patentable modification; however, such changes may impart patentability to a process if the ranges claimed produce a new and unexpected result which is different in kind and not merely in degree from results of prior art; such ranges are termed "critical" ranges, and applicant has burden of proving such criticality; even though applicant's modification results in great improvement and utility over prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art; more particularly, where the general conditions of the claim are disclosed in the prior art, it is not inventive to discover optimum or workable ranges by routine experimentation. *In re Aller et al.* 105 USPQ 233.

It is well established that merely selecting proportions and ranges is not patentable absent a showing of criticality. *In re Becket*, 33 U.S.P.Q. 33 (C.C.P.A. 1937). *In re Russell*, 439 F.2d 1228, 169 U.S.P.Q. 426 (C.C.P.A. 1971).

It is a general rule that merely discovering and claiming a new benefit of an *old* process cannot render the process again patentable. Nor can patentability be found in differences in ranges recited in the claims. When the difference between the claimed invention and the prior

⁹ See the first paragraph on page 46.

Art Unit: 1616

art is some range or other variable within the claims, the applicant must show that the particular range is *critical*, generally by showing that the claimed range achieves unexpected results relative to the prior art range. *In re Woodruff*, 16 USPQ2d 1934.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982).

Accordingly, the burden of proof is upon applicants to show that instantly claimed subject matter is different and unobvious over those taught by prior art. See *In re Brown*, 173 USPQ 685, 688; *In re Best*, 195 USPQ 430 and *In re Marosi*, 218 USPQ 289, 293.

In absence of any criticality and/or unexpected results, presently claimed invention is considered *prima facie* obvious over the prior art of record.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 1616

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**SABIHA QAZI, PH.D
PRIMARY EXAMINER**